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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,323	12/04/2003	Michael J. Caplan	2002834-0232	8163

7590 05/18/2005

PATENT GROUP
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EXAMINER

HUYNH, PHUONG N

ART UNIT PAPER NUMBER

1644

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/728,323		CAPLAN, MICHAEL J.	
	Examiner		Art Unit	
	Phuong Huynh		1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 34-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

I. Claims 34-44 are pending.

Election/Restrictions

II. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 36 and 38-44, drawn to a composition comprising dead *E coli* containing therein at least one modified allergen differs from that of a wild-type allergen, the modified allergen differs from that of a wild-type food allergen wherein the wild-type allergen is **peanuts**, and a pharmaceutical acceptable carrier, classified in Class 424, subclass 184.1, 169.1.
2. Claims 36 and 39-44, drawn to a composition comprising dead *E coli* containing therein at least one modified allergen differs from that of a wild-type allergen, the modified allergen differs from that of a wild-type food allergen wherein the wild-type allergen is **milk**, and a pharmaceutical acceptable carrier, classified in Class 424, subclass 184.1, 169.1.
3. Claims 36 and 39-44, drawn to a composition comprising dead *E coli* containing therein at least one modified allergen differs from that of a wild-type allergen, the modified allergen differs from that of a wild-type food allergen wherein the wild-type allergen is **eggs**, and a pharmaceutical acceptable carrier, classified in Class 424, subclass 184.1, 169.1.
4. Claims 36 and 39-44, drawn to a composition comprising dead *E coli* containing therein at least one modified allergen differs from that of a wild-type allergen, the modified allergen differs from that of a wild-type food allergen wherein the wild-type allergen is a specific **dairy product other than milk or egg**, and a pharmaceutical acceptable carrier, classified in Class 424, subclass 184.1, 169.1.

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5. Claims 36 and 39-44, drawn to a composition comprising dead *E coli* containing therein at least one modified allergen differs from that of a wild-type allergen, the modified allergen differs from that of a wild-type food allergen wherein the wild-type allergen is a specific **seafood**, and a pharmaceutical acceptable carrier, classified in Class 424, subclass 184.1, 169.1.
6. Claims 36 and 39-44, drawn to a composition comprising dead *E coli* containing therein at least one modified allergen differs from that of a wild-type allergen, the modified allergen differs from that of a wild-type food allergen wherein the wild-type allergen is **nuts other than peanuts**, and a pharmaceutical acceptable carrier, classified in Class 424, subclass 184.1, 169.1.
7. Claims 36 and 39-44, drawn to a composition comprising dead *E coli* containing therein at least one modified allergen differs from that of a wild-type allergen, the modified allergen differs from that of a wild-type food allergen wherein the wild-type allergen is a **specific fruit**, and a pharmaceutical acceptable carrier, classified in Class 424, subclass 184.1, 169.1.
8. Claims 37 and 39-44, drawn to a composition comprising dead *E coli* containing therein at least one modified allergen differs from that of a wild-type allergen, the modified allergen differs from that of a wild-type allergen wherein the wild-type allergen is a specific **venom**, and a pharmaceutical acceptable carrier, classified in Class 424, subclass 184.1, 169.1.
9. Claims 37 and 39-44, drawn to a composition comprising dead *E coli* containing therein at least one modified allergen differs from that of a wild-type allergen, the modified allergen differs from that of a wild-type allergen wherein the wild-type allergen is a **latex**, and a pharmaceutical acceptable carrier, classified in Class 424, subclass 184.1, 169.1.

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Linking claims 34-35 will be examined along with Groups 1-9 if any one of said Groups is elected.

Claims 34-35 link inventions 1, 2, 3, 4, 5, 6, 7, 8 or 9. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 34-35. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because:

Inventions of Groups 1-9 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the products such as modified specific food allergen, modified venom and modified latex in a composition comprising dead *E coli* containing therein said modified allergen as claimed differ with respect to its structure, and biochemical properties. Therefore, they are patentably distinct. The specification does not disclose that the claimed composition comprising dead *E coli* containing therein modified peanut allergen can be used to treat any other allergy such as allergy from milk, eggs, seafood, nuts, dairy products, fruits bee venom and latex or vice versa. A prior art search also requires a literature search. Because a search of all distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the examiner.

- III. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods

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comprising the distinct method steps. A prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

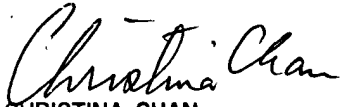
- IV. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- V. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.
- VI. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

May 13, 2005


CHRISTINA CHAN
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